ORIGINAL ARTICLE

Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place

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Background: Over the past five years, in most hospitals in England and Wales, incident reporting has become well established but it remains unclear how well reports match clinical adverse events. International epidemiological studies of adverse events are based on retrospective, multi-hospital case record review. In this paper the authors describe the use of incident reporting, pharmacist surveillance and local real-time record review for the recognition of clinical risks associated with hospital inpatient care.

Methodology: Data on adverse events were collected prospectively on 288 patients discharged from adult acute medical and surgical units in an NHS district general hospital using incident reports, active surveillance of prescription charts by pharmacists and record review at time of discharge.

Results: Record review detected 26 adverse events (AEs) and 40 potential adverse events (PAEs) occurring during the index admission. In contrast, in the same patient group, incident reporting detected 11 PAEs and no AEs. Pharmacy surveillance found 10 medication errors all of which were PAEs. There was little overlap in the nature of events detected by the three methods.

Conclusion: The findings suggest that incident reporting does not provide an adequate assessment of clinical adverse events and that this method needs to be supplemented with other more systematic forms of data collection. Structured record review, carried out by clinicians, provides an important component of an integrated approach to identifying risk in the context of developing a safety and quality improvement programme.

Over the past 20 years epidemiological studies based on case record review have shown that the chance of a patient being exposed to harmful medical practice during admission to hospital in a developed country is disturbingly high.[1–6] The studies are not strictly comparable, but overall it seems that patients have a 2.5–8% chance of suffering a preventable adverse event in relation to a hospital admission.[2 4–8]

Considerable investments have been made to devise methods to detect actual and potential adverse events in health care in order to address risk and improve patient safety. Most of this effort has been concentrated on systems of incident reporting which, once set up, are relatively low cost to maintain. In 2002, for England and Wales, the Department of Health set up the National Patient Safety Agency which is striving to identify significant problems in care using a national anonymous reporting system. This has been successful in defining several important sources of potential harm to patients such as intravenous injections of potassium chloride and the misplacement of nasogastric tubes.[9] However, there is limited reporting of issues arising from clinical treatment and overall doctors provide only about 10% reports. Furthermore, information on details of contributory factors and preceding events, important for understanding and future prevention at a local level, is often lacking in such systems.

This study was designed to gain a better understanding of the number and types of problems in hospital care identified by three independent systems—the hospital confidential incident reporting system, proactive surveillance of medication errors by pharmacists and real-time case record review—applied to a defined cohort of patients admitted to a district general hospital. The contribution of pharmacists was regarded as particularly important as medication error features prominently in reported studies of adverse events.[10 11] The overall objective was to examine the value of each of these methods for detecting and describing adverse events and potential adverse events in hospital practice with a view to explaining their respective contribution within a safety and quality improvement programme.

METHODS

Aim

To assess three practical methods of detecting adverse events and potential adverse events in order to consider their respective contributions to information on safety and quality in a designated hospital.

Design

Data were collected, prospectively, on the same patient cohort, in an acute care hospital using three sources of information. This allowed us to compare the number and types of adverse events and potential adverse events and the quality of information recorded by each method.

Setting

The study was undertaken in an 850-bedded district general hospital which receives around 40 000 admissions per year. The hospital trust covers a full range of medical and general surgical specialties backed up by full intensive care facilities. Within the trust, the overall annual incident reporting rate is 4% admissions, a number that is comparable with the UK average of 4.9%.

Box 1 Definitions of adverse event and potential adverse event

An *adverse event* is an unintended injury or complication, caused by healthcare management rather than the disease process, which prolonged the admission or led to disability at discharge or death.

A *potential adverse event* is an undesirable event in health care management which could have led to harm or did so but had no impact on duration of admission or disability at discharge.

Patients/participants

Three separate sets of data were collected independently on 288 consecutively discharged or deceased patients from three general medical and three general surgical teams. The teams were selected by the head of risk management and all agreed to participate. Data were collected on all consecutively discharged or deceased adult patients over periods of 2–3 weeks for each clinical team. Only adverse events and potential adverse events occurring *during* the index admission were included in this study.

Sources of data

In an effort to build as far as possible on existing resources within the hospital trust information was sought from the risk management department, the hospital senior pharmacist and the medical and surgical firms in the hospital. In addition to record review, two suitable data sources for the detection of adverse events and potential adverse events were identified—(1) the hospital confidential incident reporting system and (2) surveillance of inpatient prescriptions and medication administration by pharmacists. These two methods of identifying problems were well established in the Trust and were not modified for this comparative study.

Details of data sources

1. In this hospital, as throughout the NHS, risk managers encourage clinical staff to report, on printed forms, incidents that may affect patients adversely. At the time of data collection they encouraged reporting of adverse healthcare events and near misses but provided no further criteria or guidelines for reporting except that it was mandatory to supply details of incidents in which security staff are involved. Reporting is confidential but not anonymous. The forms contain both mandatory data fields and space for free text. During the periods of data collection there were neither additional incentives nor specific encouragements to enhance reporting.

2. Hospital pharmacists attend the wards on weekdays during normal working hours to ensure continuity of pre-admission medications and to detect prescribing errors. After discussion with ward doctors errors and omissions are corrected on the prescription charts. For each intervention a brief record is made on a standardised form. The forms related to the care of the 288 patients entered into the study were collected and analysed centrally in the pharmacy.

3. Specialist registrars (senior residents) monitored by external reviewers assessed all case records within 10 days of discharge of consecutively discharged or deceased patients from the participating firms. The method of review was adapted from that described previously.[12] The occurrence of an adverse event or potential adverse event was determined for each case. Each event was classified according to the stage of care and a mutually exclusive problem category (diagnosis, overall assessment of patient's condition including comorbidities, technical problems occurring during a procedure, infection-related, general problems with ongoing monitoring and management of patients and medication-related problems). Record review was also carried out by members of the clinical team caring for the patients. For medical patients these data have been presented in detail elsewhere[13] and for surgical patients a paper is in preparation. Overall the external assessors found similar numbers of recordable events but the correlation between their findings was poor ($\kappa<0.2$). In this report we have used the data collected by the external assessors. A summary of the data fields of each of three sources is provided in table 1.

RESULTS

Data collected from incident reports

In total 11 incident reports were filed on the 288 patients included in the search (4%). None caused significant harm to the patients and all were classified as potential adverse events. Doctors and nurses were directly involved in the occurrence of four potential adverse events(1.4% of admissions). They included delay in cross-matching blood for a patient requiring surgery; poor clinical hand over of a patient from accident and emergency to ward staff; a fall causing a bruised head that required medical assessment and an intravenous cannula (Venflon) misplaced in the brachial artery. Of the other reports five concerned falls without significant injury and two episodes in which security staff were called in relation to absconded or aggressive patients. The incidents were reported by nurses in nine cases, a security guard in one case and a doctor in one case.

Surveillance of data collected by pharmacists

Pharmacists identified 30 potential adverse events during the 288 admissions. The classification of medication errors is mutually exclusive. The most common problems related to failure to prescribe regular or indicated medication (15/30) and failure to prescribe the correct dose of a drug (9/30) (table 2).

Table 1 Summary of data fields for each method

Data field	Incident reporting	Surveillance by pharmacists	Rapid record review
Patient demographics	X	X	X
Date and time of event	X	X	X
Classification of stage of care		X	X
Classification of type of problem		X	X
Indication of staff group involved		X	X
Section on contributory factors			X
Section for preventative measures	X	X	X
Allocation for free text description	X	X	X
Potential to detect both AE and PAE	X	X	X
Opportunity to review all aspects of care	X		X

AE, adverse event; PAE, potential adverse event.

Table 2 Classification of all errors detected by pharmacy surveillance according to data collection form

Frequency of types of errors		
Error type	**n**	**%**
Failure to prescribe	15	50%
Incorrect dosage regimen	9	30%
Failure to monitor drug levels	1	3%
Selection of specific drug	2	7%
Incorrect route of administration	1	3%
Inappropriate duration of therapy	1	3%
Failure to act on monitoring	1	3%
Total	30	100%

Data collected using real-time record review

The records of 288 consecutively discharged medical and surgical patients were reviewed. Twenty six (9%) patients suffered an adverse event and 40 (14%) a potential adverse event during the index admission of which three adverse events and 11 potential adverse events were associated with medications. Other commonly occurring events included inadequate clinical monitoring and management (17/66), technical problems with a procedure (9/66), infection-related problems (8/66) and failure to arrange adequate follow-up or care at discharge (7/66).

Collating the data

This study was not designed to provide an epidemiological comparison between the three data sources but to illustrate how problems in providing safe care may be collected and analysed by clinical teams. To evaluate the potential value of these methods, an appreciation of both the number and type of events colleted by each is important (fig 1).

No data source detected all adverse events or potential adverse events. Although there was some overlap between the three data sources, most events were found by only one of the three methods. One incident report overlapped, in part, with a potential adverse event detected by record review. This was failure to nurse a drunk and confused patient adequately; as a result he was injured in a fall. None of the adverse events detected by record review was reported by incident reporting. The other three clinical incidents found by the incident reporting system were not detected by record review. In these cases it is unlikely that there was an explicit entry in the patient record describing the incident.

Range of problems identified

Problems arising from the prescribing and administration of medications and the monitoring of their side-effects comprised one half of the total number of events recorded. In descending order, the remainder comprised: general ward care, hospital-acquired infection, assessment and management of comorbidities, technical hitches and diagnostic error or delay (fig 2).

Detection of medication errors

Pharmacists detected prescription/drug errors affecting 30 (10%) patients all of which constituted potential adverse events. Three of these overlapped with the 14 medication errors detected by record review. No drug-related events were reported via incident reporting.

Pharmacists most commonly reported failure to prescribe regular or indicated medication (15/30) and failure to prescribe correct doses (9/30). They also found instances of not selecting the most appropriate drug and failing to indicate the duration of treatment or the correct route of administration.

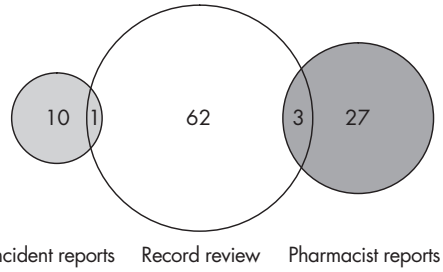

Figure 1 Incidents detected by the three methods.

Review of case records detected incidents related to failure to monitor the effects of medication adequately (5/14) (for example, monitoring of electrolyte status in patients taking diuretics); inappropriate prescriptions of medications/intravenous fluids (4/14) (for example, normal saline administered to a patient with hyponatraemia secondary to SIADH); and polypharmacy leading to side-effects in elderly patients (4/14) (for example, patient falling after being prescribed three drugs for the treatment of hypertension—subsequently shown to have a marked postural drop in blood pressure).

Quality of information obtained by each method

Record review covered the widest range of events and the information obtained was more detailed than that recorded by pharmacists even when addressing the same problems. Data available from incident reports were less structured and less complete than material gained from record review or pharmacy surveillance. Although incident reports often included considerable detail some data fields were usually left blank. Assessors undertaking record review were able to supplement details underlying incidents by discussing problems with members of clinical teams. This was particularly powerful in one case in which a patient was admitted to intensive care immediately after undergoing a left hemi-colectomy. The operative record suggested that the procedure was technically difficult and with equipment failure of a stapling device. Discussion with assistant surgeons revealed a number of issues including a prolonged delay before starting the procedure, communication failures, problems with teamwork and inadequate training in use of technical equipment.

DISCUSSION

In the UK the recognition that about 5% patients suffer a preventable adverse event during a hospital admission[5] led to

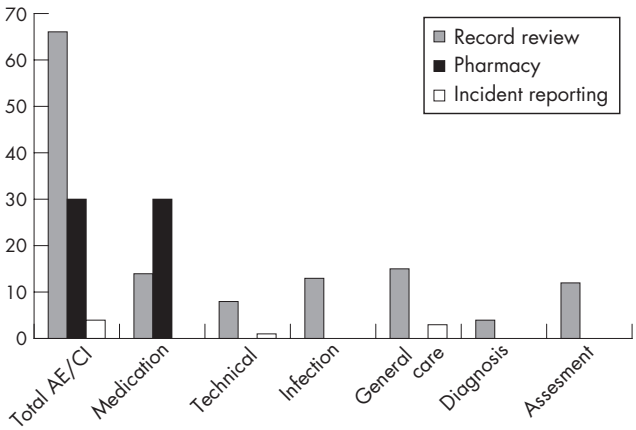

Figure 2 Illustration of the types of events detected by the three methods.

several initiatives by the Department of Health. The National Reporting and Learning System (NRLS)[14] established by the National Patient Safety Agency (NPSA)[9] has the highest profile. Incidents reported to nine types of NHS Trust (ranging from acute general hospitals to community optometry), are relayed centrally for classification and analysis. In the first full year of operation more than half a million reports were received of which 79% came from acute hospital Trusts. Such figures suggest that incident reporting is likely to provide sufficient information regarding problems in hospital care. However the first report of the NPSA showed that only 25% of incidents were related to medical care[15] and only about 10–15% came from doctors (personal communication by S Osborn and S Williams, Joint Chief Executives in response to a question at an NPSA meeting).

In this small study we found that reported incidents involved 4% patients admitted to general medical and general surgical wards. In accord with the data collected by the NPSA, falls comprised half the number of incidents reported. None of the reported incidents caused significant harm (that is, they were classified as potential adverse events). In contrast review of case records revealed adverse events affecting 9% of patients and potential adverse events were identified in a further 14% records. The underreporting of adverse events and potential adverse events has been discussed in other studies[16–18] especially in relation to adverse drug events.[19–21]

In this paper we demonstrate how local studies, in real-time, within a single hospital, can yield useful information and that audit by case record review is a particularly powerful means of detecting adverse events and potential adverse events. It allows the incidence of adverse events and potential adverse events to be calculated as the denominator is immediately available. Detailed information can be recorded in a structured manner that facilitates analysis.[13] Moreover, because the reviews were undertaken shortly after the discharge of patients contributory factors could be determined and recorded. Comments from the members of the clinical team involved in the review process were found to be particularly helpful when considering how to grapple with the issues revealed.

O'Neil *et al* showed house staff reporting may be as effective as retrospective record review undertaken by external assessors.[16] We have taken this a step further by combining in-house methods of detecting adverse events and potential adverse events. In this report we include adverse events and potential adverse events occurring only during the index admissions in order to allow valid comparisons with incident reporting and pharmacists' surveillance. In fact some adverse events and potential adverse events initiated before admission to hospital were identified. This adds to the value of real-time case record review.[13 22]

Further studies will be needed to determine the optimal method for case record review. In this report we have used data collected by specialist registrars (senior residents) backed up by experienced external clinical assessors. Elsewhere we have reported on accumulated data gathered by external assessors, senior residents, senior nurses and ward pharmacists.[13] The quality of the data from record review in this study is less robust than it might have been because the time for the training of local staff was very limited. However, we have shown that if local staff are required to undergo training and to undertake this sort of audit on an annual basis, useful snapshots of local practice can be obtained. Although reliability of the data collected by experienced external experts may arguable be better, it is our experience that data collected by local clinicians is more powerful in driving change of practice due to a greater sense of ownership of both the data and the problems identified. We calculated the time spent by local staff involved in this study and showed that it was no more than 0.5% to 0.9% of total annual working hours.

Pharmacists in many institutions routinely review inpatient's prescription charts and correct errors. This source of information appears not to be often used by risk managers. In this study pharmacy surveillance detected the highest number of drug events all of which were classified as potential adverse events. Harm to patients was prevented in all cases. The events were well described but information on contributory factors or means of prevention was not available. It would be difficult to ascertain these from reviews by pharmacist as they rely primarily on information recorded on the medication chart. It is important to note that pharmacists recognise and prevent the initiation of problems whereas review of case records reveals ongoing problems that cause or have the potential to cause adverse events. Such problems arise primarily from inadequacies in monitoring the effects and interactions of medications. It has been shown possible to integrate the two systems by using electronic ''triggers'' as markers for adverse drug events.[23 24]

The main aim of local data collection should be to share learning from errors and use the information obtained to guide initiatives to improve patient safety. The results of this study highlight the potential value of both real-time record review and observations by ward pharmacists and suggest that risk management and safety committees need to draw on a wider range of data sources than are commonly used at present. More adverse events and potential adverse events are detected by local real-time record review than other methods. Moreover this method has the added benefit of involving clinicians in a direct examination of team practices in relation to patient safety. In addition, of the methods described, real-time record review has the potential to provide detailed information across a range of problems. This is essential to maximise local learning from error. Since the completion of this study both the means of collecting data and the training of clinicians has been refined. In the UK real-time record review is currently used in a small number of acute care trusts as part of clinical audit.

In France in a very careful and detailed study Michel *et al* has shown that external assessors may detect similar numbers of adverse events prospectively by visiting wards repeatedly over one month or by undertaking retrospective case record review after patients have been discharged.[7] These studies were undertaken in seven hospitals. Under the conditions of the NHS it would be difficult to recruit sufficient external assessors and we believe that there are significant advantages in getting local staff to examine local problems in order to define local solutions.[13]

The introduction of an electronic medical record opens new avenues for detecting problems in hospital care. Systematic ''mining'' of data, electronically, and the use of ''triggers'' may lead to closer analysis of individual episodes. The potential of these developments has yet to be ascertained but some studies of electronic recognition of adverse drug errors have been promising.[10 11]

CONCLUSION

This study adds weight to the emerging argument that reporting of incidents is not enough to gain a comprehensive picture of areas of risks in clinical care within a healthcare Trust. Instead a portfolio of systems should be used and these integrated in a systematic way. This study was not powered to make conclusive statements on rates of detection of the methods investigated but does illustrate the need for an integrated approach to identifying risks and highlights the potential use of structured case record review by clinicians as part of this process

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Conflicting interests: None declared.

Ethics approval: Proposal for this study were submitted to external advisers. The Brent Medical Ethics Committee gave their approval in October 2003 (BEC 1060).

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ECHO

Coronary heart disease mortality in Ireland

Please visit the *Quality and Safety in Health Care* website [www.qshc.com] for a link to the full text of this article.

Between 1985 and 2000 coronary heart disease (CHD) mortality rates in Ireland fell by 47% in those aged between 25–84 years. This resulted in 3763 fewer ''observed'' deaths in 2000 compared with the expected number given the rates in 1985 (8681 expected minus 4918 observed).

Overall, the cell based mortality model IMPACT predicted 3449 fewer deaths, about 92% of the observed CHD mortality fall. The remaining 8% were attributed to other unmeasured factors. 43.6% of the observed decrease in mortality was attributed to medical and surgical treatments, particularly secondary preventative therapies and treatment of heart failure. 48.1% of the fall was attributable to changes in risk factors including substantial reductions in smoking and cholesterol, but this was offset by increases in obesity, diabetes, and reduced physical activity.

Changes in the three classic cardiovascular risk factors (smoking, cholesterol, and blood pressure) contributed 61.9% of the total CHD mortality decrease—consistent with studies in other developed countries. A significant contribution of the reduction in mortality attributable to risk factors reflected a moderate decrease in smoking prevalence, from 34% to 29% (a 5% absolute risk reduction). However, almost 30% of the mortality decrease came from a comparatively small reduction (4.6%) in population total cholesterol levels. The adverse trends in obesity, diabetes, and physical activity contributed over 500 additional deaths in 2000, cancelling out over half the benefit from 15 years of cholesterol improvement.

These results emphasise the importance of a comprehensive strategy that maximises population coverage of effective treatments, and that actively promotes primary prevention, particularly tobacco control and a cardioprotective diet.

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